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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,627	02/26/2004	Howard Kaufman	19240.461	7662

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EXAMINER
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BERTOGLIO, VALARIE E

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/789,627

Applicant(s)

KAUFMAN ET AL.

Examiner

Valarie Bertoglio

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-65 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                           |                                                                                        |
|-----------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                          | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____                                                |

*Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-25, drawn to a composition for delivering a diagnostic agent to a target cell comprising a microorganism that has on its cell surface an exogenous molecule that binds the target cell and an agent wherein the agent is a diagnostic agent, classified in class 424, subclass 93.1.
- II. Claims 1-25, drawn to a composition for delivering a labeling agent to a target cell comprising a microorganism that has on its cell surface an exogenous molecule that binds the target cell and an agent wherein the agent is a labeling agent, classified in class 424, subclass 93.1.
- III. Claims 1-25 and 32, drawn to a composition for delivering a preventative agent to a target cell comprising a microorganism that has on its cell surface an exogenous molecule that binds the target cell and an agent wherein the agent is a preventative agent, classified in class 424, subclass 93.1.
- IV. Claims 1-26,30, 31, 33-56 and 62-65 drawn to a composition for delivering a therapeutic agent to a target cell comprising a microorganism that has on its cell surface an exogenous molecule that binds the target cell and a therapeutic agent wherein the therapeutic agent is not a nucleic acid and a method of using said composition for treating neoplasia, classified in class 514, subclass 2.
- V. Claims 1-29, 33-61 and 65, drawn to a composition for delivering a therapeutic agent to a target cell comprising a microorganism that has on its cell surface an exogenous molecule that binds the target cell and a therapeutic agent wherein the

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therapeutic agent is a nucleic acid and a method for using said composition in treating neoplasia, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-V are patentably distinct products that are used in distinct processes that have different mechanism and purpose. Invention I is drawn to a composition for delivering a diagnostic agent that can be used to determine the presence of a disease state. Invention II is drawn to a composition for delivering a labeling agent to a cell such that the cells can be visualized. Invention III involves a composition for delivering a preventative agent that acts to prevent disease rather than treat an ongoing disease as in Inventions IV and V. Inventions IV and V are drawn to a composition for delivering a therapeutic agent, however, Invention IV uses agents other than nucleic acids. Invention V uses a nucleic acid agent in treatment that requires different technical considerations and is classified differently from the therapeutic agent of Invention IV. The compositions of Invention I-III have distinct uses from one another and from Inventions IV and V. The protocols and reagents required for use of each of the compounds of Inventions I-V are materially distinct and separate.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Claim 20 is generic to the following disclosed patentably distinct species:

a) bowel cancer cell

- b) breast cancer cell
- c) cervical cancer cell
- d) colon cancer cell
- e) esophageal cancer cell,
- f) head cancer cell
- g) liver cancer cell
- h) lung cancer cell
- i) neck cancer cell
- j) stomach cancer cell.

The species are independent or distinct because each is drawn to a distinct and non-obvious type of cancer cell with distinct characteristics and requirements for detection and treatment. Each different type of cancer cells expresses a characteristic set of gene and antigens on the cell surface. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Claims 23 and 54 are generic to the following disclosed patentably distinct species:

- a) CAK1
- b) CDK4
- c) CDR2
- d) CEA
- e) disialoganglioside GD2
- f) Her-2
- g) LEA
- h) MAGEs
- i) MUC1
- j) p21
- k) podocalyxin
- l) Ras
- m)UK114
- n)WT1.

The species are independent or distinct because each is drawn to a distinct antigen that will bind to distinct exogenous molecules on the surface of the claimed microorganism. Furthermore, no each antigen is relevant to various species of cancer as set forth in the preceding species restriction. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and

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a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Valarie Bertoglio  
Examiner  
Art Unit 1632